

**REMARKS**

Claims 1-46 are pending in the application and are currently rejected. Claims 1, 17, 19, 22, 23, 33 and 42 have been amended. In light of the amendments and remarks herein, reconsideration of claims 1-46 is respectfully requested.

**Amendments to the Specification**

The Specification has been amended to address the Examiner's objections. No new matter has been added to the Specification.

**Amendments to the Claims**

While Applicants believe that the previously presented claims are patentable over all of the art cited in the Office Action as well as all other references submitted by Applicants, the claims have nonetheless been amended as follows in order to expedite allowance of the claims. The amendments are therefore made without prejudice or disclaimer, and Applicants reserve the right to pursue the original scope of the claims as provided prior to the cancellation or amendments, such as through continuation practice.

Claim 1 is amended to recite an apparatus as referred to in the dependent claims.

Claims 17 and 19 are amended to clarify the relative direction of the shape being claimed.

Claim 22 is amended to clarify the radiation emitting element to which the claim refers.

Claim 23 is amended to correct the dependency from Claim 19 to Claim 18, which supplies the proper antecedent basis addressed by the Examiner.

Claim 33 is amended to address the Examiner's objection to the claim.

Claim 42 is amended to correct a typographical error.

As such, the amendments to claims 1, 17, 19, 22, 23, 33 and 42 do not add any new matter.

**Double Patenting**

The Examiner provisionally rejected Claims 1-3 of the present Application based on obviousness-type double patenting as being unpatentable over claims 6 and 7 of copending U.S. Patent Application No. 10/776,686 (the “‘686 Application”).

The differences between Claim 1 in the present Application and Claim 1 of the ‘686 Application are not obvious. Each claimed invention is different in kind and is, therefore, patentably distinct. For example, Claim 1 of the present application recites an apparatus having “at least one radiation emitter coupled to the body to irradiate a portion of the oral cavity with phototherapeutic radiation in *at least two separate spectral bands*.” On the other hand, Claim 1 of the ‘686 Application, from which all other cited claims from the ‘686 Application depend, recites “at least one radiation emitting element coupled to the body to irradiate a portion of the oral cavity with phototherapeutic radiation *along multiple directions*.” These two independent claims are directed to two distinct concepts that are not obvious in light of each other. The present application claims a device that is capable of irradiating tissue in the oral cavity using distinct spectral bands to, e.g., “treat the same conditions more effectively or to treat two different conditions.”<sup>1</sup> (See Application ¶ 086.) The ‘686 Application as filed claims a device capable of emitting radiation in multiple directions to, e.g., selectively direct optical radiation delivered from an oral appliance to different regions of the oral cavity depending on the desired treatment regimen. (See ‘686 Application ¶ 080.) Claims 6 and 7 of the ‘686 Application, which also dependently claim irradiating tissue using multiple spectral bands, also are not obvious because they incorporate the non-obvious limitations of Claim 1, which are patentably distinct over Claim 1 of the present Application.

Claims 2 and 3 of the present Application, which depend on Claim 1, are patentably distinct for the same reasons that Claim 1 is patentably distinct.

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<sup>1</sup> Unless specifically noted otherwise, any use of examples in this response is intended to be exemplary only and is not intended to limit the scope of any present claim or any claim that may issue from this application.

The Examiner also provisionally rejected Claims 1-3 of the present Application based on obviousness-type double patenting as being unpatentable over claims 2 and 3 of copending Application No. 10/776,687 (the “‘687 Application”).

The differences between Claim 1 in the present application and Claim 1 of the ‘687 Application are not obvious. Each claimed invention is different in kind and is, therefore, patentably distinct. Claim 1 of the ‘687 Application, from which each of Claims 2 and 3 depend, recites an “emitter being *capable of delivering radiation to a region of facial tissue.*” These two Applications are directed to two independent inventions. As noted above, the present application claims a device that is capable of irradiating tissue in the oral cavity using distinct spectral bands to, e.g., “treat the same conditions more effectively or to treat two different conditions.” (See Application ¶ 086.) On the other hand, the ‘687 Application as filed claims a device capable of emitting radiation to facial tissue from the oral cavity to, e.g., treat acne by directly radiating from within the oral cavity out toward the target tissue instead of treating acne by radiating the affected skin. (See ‘687 Application ¶ 0131.) Dependent claims 2 and 3 of the ‘687 Application, although they also recite “separate spectral bands” and “different spectral bands” respectively, do not render Claim 1 in the present application obvious, because those claims also include the patentably distinct limitations of Claim 1 of the ‘687 Application.

Claims 2 and 3 of the present Application are patentably distinct for the same reasons that Claim 1 is patentably distinct.

The Examiner also provisionally rejected Claims 1-3 of the present Application based on obviousness-type double patenting as being unpatentable over claims 5 and 6 of copending Application No. 10/776,936 (the “‘936 Application”).

The differences between Claim 1 in the present application and Claim 1 of the ‘936 Application are not obvious. Each claimed invention is different in kind and is, therefore, patentably distinct. Claim 1 of the ‘936 Application, from which each of Claims 5 and 6 depend, recites “at least one radiation emitter coupled to the body *to irradiate with phototherapeutic radiation a portion of the oral cavity other than tissue in contact with the bristles.*” These two Applications are directed to two independent inventions. As noted above, the present application

claims a device that is capable of irradiating tissue in the oral cavity using distinct spectral bands to, e.g., “treat the same conditions more effectively or to treat two different conditions.” (See Application ¶ 086.) On the other hand, the ‘936 Application as filed claims a device capable of emitting radiation in a direction other than the direction of the bristles to, e.g., emit radiation in a direction other than towards the hard tissue of teeth to treat other tissues in the oral cavity while the bristles are in contact with the teeth. (See ‘936 Application ¶ 081.) Dependent claims 5 and 6 of the ‘936 Application, although they also recite “separate spectral bands” and “different spectral bands” respectively, do not render Claim 1 in the present application obvious, because those claims also include the patentable distinct limitations of Claim 1 of the ‘936 Application.

Claims 2 and 3 of the present Application are patentably distinct for the same reasons that Claim 1 is patentably distinct.

The Examiner also provisionally rejected Claims 1-3 of the present Application based on obviousness-type double patenting as being unpatentable over claims 2 and 3 of copending Application No. 10/777,020 (the “‘020 Application”).

The differences between Claim 1 in the present application and Claim 1 of the ‘020 Application are not obvious. Each claimed invention is different in kind and is, therefore, patentably distinct. Claim 1 of the ‘020 Application, from which each of Claims 2 and 3 depend, recites “a body sized and shaped so as to fit at least partially in a user’s mouth and adapted to conform to the shape of at least a portion of the oral cavity.” These two Applications are directed to two independent inventions. As noted above, the present application claims a device that is capable of irradiating tissue in the oral cavity using distinct spectral bands to, e.g., “treat the same conditions more effectively or to treat two different conditions.” (See Application ¶ 086.) On the other hand, the ‘020 Application as filed claims a device, e.g., such as a mouthpiece that is capable of fitting the portions of the oral cavity between the teeth and the walls of the oral cavity or other body portions such as a user’s tongue, the roof of a user’s mouth (hard and/or soft palate), and/or the floor of the oral cavity (for example, beneath a user’s tongue). (See ‘020 Application ¶ 067.) Dependent claims 2 and 3 of the ‘020 Application, although they also recite “separate spectral bands” and “different spectral bands” respectively, do

not render Claim 1 in the present application obvious, because those claims also include the patentable distinct limitations of Claim 1 of the '020 Application.

Claims 2 and 3 of the present Application are patentably distinct for the same reasons that Claim 1 is patentably distinct.

**Claim Rejections - 35 U.S.C. § 112**

Claims 17, 19 and 23 were rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. Applicants have amended those claims.

**Claim Rejections - 35 U.S.C. § 102**

Claims 1-10, 27, 31-32, 34-42 and 46 stand rejected under 35 U.S.C. §102(b) as being anticipated by WO 98/06456 to Chen et al. (herein "Chen"). These claims are novel, however, because Chen fails to disclose all of the elements recited in the claims. For example, Claim 1 recites "at least one radiation emitter coupled to the body to irradiate a portion of the oral cavity with phototherapeutic radiation in at least two separate spectral bands." Chen does not teach an oral device that irradiates a portion of the oral cavity in at least two separate spectral bands.

The Examiner states that U.S. Patent 5,445,608 (the "'608 patent'"), which is incorporated by reference in Chen, supplies the missing element of an oral device having at least one radiation emitter to irradiate phototherapeutic radiation in at least two spectral bands. The '608 patent discloses an invasive probe for treating, e.g., tumors, that may operate "at two or more wavelengths." ('608 Patent Cols. 1:15-36, 8:37-45 and Abstract.) Chen's oral appliance does not include or teach that feature. Chen expressly discloses a device that operates differently than the probe and teaches away from combining the features of the probe and oral appliance. For example, Chen states that "the design and shapes of probes disclosed in [the '608 patent] are not well suited for use in administering PDT for extended periods of time inside a patient's mouth." (Chen page 2 lines 28-30.)

Further, by incorporating the '608 patent by reference, Chen discloses a probe that is capable of operating using multiple wavelengths, but has not disclosed an oral appliance having such capability. Chen fails to disclose a device that anticipates the claimed invention due to the lack of an express disclosure, a motivation to combine the aspects of the disclosed probe and aspects of the disclosed mouthpiece to obtain the claimed features of the claimed invention, and the express teaching that the probe is ill-suited for use in the oral cavity.

Additionally, Chen expressly and repeatedly discloses operation of an oral appliance at only a single waveband. Chen teaches the application of a photoreactive agent and the illumination of the agent after it is absorbed into tissue in the oral cavity. For example, Chen discloses the application of a photoreactive agent that has a characteristic waveband of wavelengths that are absorbed and that is placed along the gum line and illuminated with "light having a corresponding waveband." (Chen page 7, lines 2-5.) Chen does not disclose the operation of an oral appliance using multiple wavebands. The limitation of Chen's device to operation using a single waveband is also clearly reflected in the claims. For example, all but one of the amended claims in Chen require "a predefined waveband that is substantially equal to a characteristic light absorption waveband of a photoreactive agent" and all of the claims require "a predefined waveband." (See Chen Independent Claims 1, 7, 12, 17, 18, 19 and 20). Consistent with Chen's specification, no claim recites multiple wavebands.

Furthermore, as noted above, Chen discloses only the illumination of photoreactive agents, and does not disclose a device as claimed in the present Application, which is capable not only of illuminating and treating tissue using multiple spectral bands but also of treating tissue without the use of a photoreactive agent. (See Application generally.)

Claims 2-10, 27, 31-32, 34-42 and 46 are novel for at least the same reasons that Claim 1 is novel.

With respect to Claims 5 and 6, Chen does not teach, either explicitly or implicitly, the use of an "optical filter for selecting a spectral band of radiation" (as recited in Claim 5) or "a plurality of optical filters for selecting a plurality of spectral bands of radiation for use in

phototherapy” (as recited in Claim 6). Instead, Chen teaches applying a photoreactive agent and applying light that has a corresponding waveband. Specifically, as noted above, Chen states:

Each type of photoreactive agent has a characteristic absorption waveband or range of wavelengths that are absorbed. Light having a corresponding waveband or range of wavelengths is then applied by fixture 20.

(See Chen at page 7, lines 2-4.) As noted above, Chen does not disclose the use of an oral appliance operating using multiple wavebands; Chen also does not disclose the application of multiple photoreactive agents at one time; and Chen does not disclose that, to correspond to the characteristic waveband of the photoreactive agent, the applied waveband must precisely correspond to the waveband, as opposed to, for example, provide a broader range of light than the characteristic absorption waveband. (Chen does claim, however, a waveband that is “substantially equal to” the characteristic absorption waveband of the photoreagent in all but one independent claim, as discussed above, but there is no disclosure of filters as a means to achieve this.) Therefore, Chen cannot be said to inherently teach the use of filters, whether or not using a polychromatic source. Chen is silent as to whether such a filter would be required or even beneficial.

With respect to Claims 7 and 8, as discussed above, Chen does not disclose an oral appliance that has readily selectable spectral bands, and, thus, the overlapping, or not overlapping of the bands is not inherent.

With respect to Claims 27 and 31, Chen does not discuss either temperature or heat dissipation. Chen also does not disclose the use of thermally conductive materials to dissipate heat. Rather, Chen discloses only the use of polymers, such as and optically transparent polyurethane or similar plastic. (See Chen page 7, lines 17-20.) Such materials are typically poor conductors of heat. As shown in attached Exhibit A (excerpt from Rodriguez, Principles of Polymer Systems, 2<sup>nd</sup> edition, McGraw Hill, New York, 1982, p. 266) the thermal conductivity of most polymers is around  $4.1 \times 10^{-4} \text{ cal sec}^{-1} \text{ cm}^{-1} \text{ K}^{-1}$  (this is equivalent to about  $0.1 \text{ Btu/ft}^{-1} \text{ hr}^{-1} \text{ F}^{-1}$ , which is midpoint of the range of thermal conductivity values cited by Rodriguez). In comparison, aluminum, which is named as an exemplary heat sink material in the application (see paragraph [0074] of the Application), is *approximately one-thousand times more thermally*

*conductive* than a typical polymer (i.e., about  $5 \times 10^{-1} \text{ cal sec}^{-1} \text{ cm}^{-1} \text{ K}^{-1}$  as shown in Exhibit B, excerpted from Bird, Stewart, Lightfoot, Transport Phenomena, John Wiley & Sons, Inc., New York, 1960, p. 249).

Accordingly Claims 1-10, 27, 31-32, 34-42 and 46 are novel and patentable over Chen.

Claims 1, 11-13, 15, 16, 18, 20-22, 26 and 44 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,862,771 to Muller (herein "Muller"). These claims are novel, however, because Muller fails to teach or suggest the elements recited in the amended claims.

Claim 1 recites an apparatus for treating tissue in an oral cavity comprising a body, a plurality of bristles coupled to the body, and "at least one radiation emitter coupled to the body to irradiate a portion of the oral cavity with phototherapeutic radiation in at least two separate spectral bands." In contrast, Muller is directed to "a toothbrush head suitable to direct incident radiation toward a surface of a tooth and to collect emitted radiation from the surface of the tooth." (See Muller, Abstract.) The Examiner states at page 6 of the Office Action that the disclosure of the bristles being transparent over two wavelength ranges (400-520 nm and 530-600 nm) implies the transmission of phototherapeutic radiation in two separate spectral bands. However, only one of those ranges is emitted by the device in Muller. The other range is light that is emitted by the tooth and detected by the device. Muller distinguishes between incident and emitted radiation. (See Muller Col. 2:38-65 (passage cited in office action.)) Muller defines incident radiation as the radiation in the range of 400-520 nm that the toothbrush directs to the tooth to impinge on the surface of the tooth to excite fluorescent emission from biological deposits on the tooth. (Muller Col. 2:21-37 and Col. 10:13-33.) The emitted radiation to which Muller refers, which is in the higher band of 530-600 nm, is the fluoresced light emitted from the biological deposits on the tooth. (Muller Col. 10:13-33.) Thus, in the cited passage, Muller discloses only a single spectral range of "incident radiation" emitted by the device and is not referring to "irradiating ... with phototherapeutic radiation in at least two separate spectral bands" as claimed.



Further, Muller does not disclose the elements of Claims 16, 18 and 20, i.e., bristles shaped to control light distribution, to transmit radiation, and to serve as a lasing element. Muller does not disclose the techniques taught by the Applicants. For example, at Paragraph 093, the Applicants disclose: .

In some embodiments of the invention, the bristles are shaped so as to allow controlled leakage of radiation at selected points. For example, FIG. 24 illustrates another embodiment of bristle 14 in the form of an optical loop. Both ends of the loop are connected to an optical radiation source 18. Light is generally contained within the loop except for at the bend where the disturbed complete or almost complete internal reflection effect allows light leakage. The bend can be positioned in a target tissue area to deliver optical radiation. Such bristles also enhance eye safety characteristics of the device because they can ensure that light is emitted only at selection portions, e.g., portions in contact with oral cavity tissue.

Muller does not require or teach these or other techniques, including the use of total internal reflection to prevent the emission of radiation from the bristles when the bristles are not in contact with tissue.

Claims 11-13, 15, 16, 18, 20-22, 26 and 44 are novel for at least the same reasons that Claim 1 is novel.

**Claim Rejections - 35 U.S.C. § 103**

*Claims 14 and 33*

Claims 14 and 33 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller (herein "Muller") in view of the knowledge of one skilled in the art. As discussed above, Muller does not disclose all elements of Claim 1 from which Claims 14 and 33 depend. Thus, Claims 14 and 33 are not obvious, because all elements of the claim are not disclosed in the combination of Muller and the knowledge in the art.

*Claims 17 and 19*

Claims 17 and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller (herein "Muller") in view of the knowledge of one skilled in the art.

As discussed above, Muller does not disclose all elements of Claim 1 from which Claims 17 and 19 depend. Thus, Claims 17 and 19 are not obvious, because claimed elements are not disclosed in the cited combination. Furthermore, also as discussed above, the shape of the bristles are not minor design considerations. The shape of the bristles can be used to control the transmission of therapeutic radiation in several respects, and the bristle shapes are inventive in nature and not merely a design consideration. (See, e.g., Application 092 and 093.)

*Claim 23*

Claim 23 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller (herein "Muller") in view of U.S. Patent 6,273,884 to Altshuler et al. (herein "Altshuler").

Claim 23 is not obvious, because there is no motivation to combine Muller and Altshuler. Muller does not disclose a need or benefit from controlling the emission of radiation when a bristle is not in contact with tissue of the oral cavity. Instead, Muller discloses a means irradiate biological deposits on teeth and detect them from their fluorescence. Muller, therefore, is concerned with using total internal reflection, e.g., in the head of the device to ensure that radiation is directed in the proper direction, but there is no teaching of a benefit to restraining that radiation once it has been properly directed at the tooth. As such, there is no motivation to combine Muller with Altshuler's teachings regarding using internal reflection to prevent the emission of radiation when a device is not in contact with the tissue being irradiated.

*Claim 24*

Claim 24 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Muller further in view of U.S. Patent Number 6,029,303 to Dewan (herein Dewan). The claim, however, is patentable because there is no suggestion or motivation by either reference to combine the references to obtain "a motion sensor and controller which controls the radiation emitter based on signals from the motion sensor" as claimed. Dewan discloses installing a motion detector for a very different purpose, i.e., as an alert to ensure, for example, sufficiently long brushing by children or the disposal of a toothbrush kept too long. (Dewan Col. 1 40-54.)

Dewan does not disclose the use of a motion sensor in conjunction with a control system for controlling a radiation emitter to treat the oral cavity. Given the distinct purpose and nature of the motion sensor in Dewan, it would not be obvious to combine Dewan and Muller, and the resulting combination would not disclose all of the elements of the claimed invention.

*Claim 25*

Claim 25 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller (herein “Muller”) in view of U.S. Patent No. 5,133,102 to Sakuma (herein “Sakuma”). The claims, however, are patentable, because even when combined Muller and Sakuma do not provide all of the elements of the claims.

As discussed above, Muller does not disclose all of the elements of independent Claim 1. Muller, the primary reference, is directed to a toothbrush head suitable to direct incident radiation toward a surface of a tooth and to collect emitted radiation from the surface of the tooth. (See Muller, Abstract.) Sakuma does not supply the teachings that are missing from the claims.

Additionally, Sakuma does not teach a contact sensor and controller that controls the radiation emitter based on signals from the contact sensor as recited in Claim 25. Sakuma teaches a simple circuit that is closed by the gripping of the handle of the toothbrush and the touching of the bristles to the teeth. The complete circuit causes “a current which passes through the user's hand and body flows into the surface of the teeth via the dental pulp tissue and tooth tissue proper.” (See Sakuma Col. 4, lines 4-9.) The “flow of electric current causes the protein organic ions of plaque on the surfaces of the teeth to become affixed to the toothbrush.” (See Sakuma Col. 4, lines 4-9.) The mechanism in Sakuma is not a contact sensor that supplies signals to a controller that controls the emitter. Sakuma does not emit radiation onto the teeth and, thus, does not include a controller that controls the emitter. Instead, the LED of Sakuma is an alarm to alert the user “that the toothbrush is operating.” (See Sakuma, Abstract.)

*Claims 27, 29 and 43*

Claims 27, 29 and 43 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Muller in view of U.S. Patent No. 4,333,197 to Kuris (herein "Kuris"). The claims, however, are patentable, because there is no suggestion or motivation to modify the toothbrush head of Muller with the ultrasonic toothbrush of Kuris. Further, even when combined, Muller and Kuris do not disclose all of the required elements of the claims.

Muller, as discussed above, does not teach all of the elements of Claim 1. Further, Muller does not teach or disclose the removal of heat or the control of temperature from the device. The Examiner states at page 9 of the Office Action that heat transfer in the device in Muller is inherent because virtually all materials have some heat transfer capacity. However, not all materials are suitable for such a purpose, because not all materials have a sufficient thermal conductivity, even though they may have some nominal ability to conduct heat. It is commonly known that the ability to conduct heat in many materials is so low that they are considered to be insulators. On the other hand, the Applicants specifically disclose an embodiment with structures having sufficient thermal conductivity to remove heat. For example, in paragraph 074, the Applicants state:

An LED, a laser diode, or a microlamp can generate heat energy that is up to 20 times higher than the generated optical energy. To accommodate unwanted waste heat, the light emitting oral appliance can include heat transfer and/or cooling mechanisms. For example, head portion 12 of the exemplary light emitting toothbrush can be at least partially formed of a heat conducting material for dissipating heat generated by the radiation source. For example, with reference to FIG. 2B, the head portion 12 can include a head frame 38 that is constructed from a material having high thermal conductivity and/or good heat capacitance and is thermally coupled to the radiation source 18 to extract heat therefrom.

In contrast, Muller is silent both as to the need to remove waste heat in his device and as to the thermal conductivity of the structures included in his device. The ability to conduct heat from the device, therefore, is not inherent in Muller.

Kuris does not disclose “at least one thermally conductive element for extracting heat from the emitter” as required by Claims 27 and 29. Kuris does not disclose removing heat from the emitter of the device. Specifically, Kuris states at Col. 4, lines 23-33:

The components disclosed in the preferred embodiment herein are of the discrete type including a plurality of resistors, capacitors and transistors and are preferably mounted on a printed circuit assembly board 40 to the rear inside area 42 of display case 18, in a conventional manner. The side walls 38 and 44 may be made of metal such as aluminum, permitting the power drive transistor 50 to be mounted directly to the side wall 44, in a conventional manner, so that any heat dissipated therein may be readily radiated to the external atmosphere.

The electronic components to which Kuris refers are not contained in the ultrasonic toothbrush. Instead, the components are part of a display case. The display case is designed to be mounted on a wall or placed on a table. Kuris teaches heat transfer from electrical components associated with the input power transformer 52 in the display case and not from either the transducer motor 60 or any ultrasound emitter located in Kuris’ toothbrush. Thus, Kuris does not teach the heat transfer elements of claims 27 and 29.

Moreover, Kuris does not teach the combination of an emitter with an ultrasound generator as required in claim 43. Kuris teaches only the use of ultrasonic energy for use in a toothbrush. Kuris does not teach the use of an ultrasound generator in a device having a body adapted to conform to at least a portion of the oral cavity, and Kuris does not teach the use of an ultrasound generator in combination with a radiation emitter. There is no teaching or suggestion in either Muller or Kuris to combine these elements, or that such a combination would compliment the hygienic process as stated at page 7 of the Office Action. Therefore, absent some stated motivation to combine the references, the combination is not obvious.

#### *Claims 28 and 30*

Claims 28 and 30 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Muller further in view of U.S. Patent Number 4,333,197 to Kuris (herein “Kuris”) and further in view of U.S. Patent Number 6,350,276 to Knowlton (herein “Knowlton”). The claims, however, are patentable because there is no suggestion or motivation by either reference to combine the device of Knowlton with the oral appliances of Muller and Kuris. In fact, Knowlton teaches

away from such an application by listing a host of potential applications that do not include treating tissues in the oral cavity. (Knowlton Col. 6:49-57.)

Furthermore, Knowlton uses radiation to reshape collagen-containing tissue, and the cooling mechanism provides a means to protect the collagen-containing tissue from thermal damage.

Fluid delivery device 13 is configured to deliver a heat transfer media 15 (also called a cooling media 15, flowable media 15 or fluid 15) to tissue interface 21, that serves to dissipate sufficient heat from the skin and underlying tissue at or near tissue interface 21 during the delivery of energy at or near this site so as to prevent or reduce thermal damage including burning and blistering. Similarly, fluid delivery device 13 may also deliver fluid 15 to and dissipate heat from energy delivery device 18 and/or template 12 to achieve a similar result.

(See, e.g., Knowlton Col. 5, lines 4-13.) There is no teaching from Muller or Kuris that suggests that the toothbrush devices of Muller or Kuris operate at sufficiently high power that tissue may be thermally damaged, including burning and blistering of tissue in contact with or irradiated by the toothbrush device, or that cooling as in Knowlton is either required or beneficial. Thus, there is no motivation to combine the references.

#### *Claim 45*

Claim 45 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Muller in further view of U.S. Patent Number 5,658,148 to Neuberger et al. (herein "Neuberger"). The claim, however, is patentable because there is no suggestion or motivation by either reference to provide a drug delivery port as claimed. The water or liquid passage disclosed in Neuberger is used for a different purpose, and there is no teaching or motivation to alter the device of Neuberger or to combine such an altered device with Muller to obtain a drug delivery port that operates using principles consistent with the disclosed operation of the device in Muller. In the specific text cited by the Examiner, Neuberger discloses a passage that delivers water or other liquid under pressure during operation. The purpose of the water or liquid is to facilitate the transfer of radiation, and not to deliver a drug. Neuberger discloses that, when liquid passes over fiber end 53 radiation will pass substantially parallel to the optical fibers due to the change in refractive index. (Neuberger Col. 4:12-25.)

Furthermore, Claims 14, 17, 19, 23, 24, 25, 27, 28, 29, 30, 33, 43 and 45 are each patentable for at least the same reasons the Claim 1 is patentable.

### CONCLUSION

In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. In the event that the amendments and remarks are not deemed to overcome the grounds for rejection, the Examiner is kindly requested to telephone the undersigned representative to discuss any remaining issues.

Respectfully submitted,

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